UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

EILEEN A BOWER, Plaintiff, v. LAWRENCE COUNTY CHILDREN AND YOUTH SERVICES; LAWRENCE COUNTY; EVA LIGHTEL, Lawrence County Children and Youth Services Caseworker; and JAMESON HEALTH SYSTEMS Defendants	CIVIL ACTION NO. 2:11-CV-00931-TFM **EXPERT REPORT OF MATTHEW KRASOWSKI, M.D., Ph.D.**

I, Matthew Krasowski, hereby submit the following opinion on behalf of the plaintiff.

EXHIBIT "D"

I. INTRODUCTION

1. I am an expert in the field of laboratory medicine and drug of abuse testing I am a Clinical Associate Professor of Pathology at the University of Iowa Hospitals and Clinics ('UIHC'), a public teaching hospital and level one trauma center associated with the University of Iowa I am currently Director of Clinical Laboratories and Medical Director of the Clinical Chemistry and Point of Service Laboratories within the Department of Pathology. I am a board-certified physician in clinical pathology (also known as laboratory medicine) and an attending pathologist for UIHC. The clinical laboratories I direct perform drug of abuse screening tests and also refer confirmatory drug of abuse testing to outside reference laboratories. My responsibilities as medical director include oversight of testing referred to outside laboratories. I have worked at UIHC since July 1, 2009

2. Prior to working at UIHC, I was an Assistant Professor of Pathology for the University of Pittsburgh and University of Pittsburgh Medical Center ('UPMC'). I was also medical director and section chief for the Toxicology and Therapeutic Drug Monitoring laboratories for UPMC – Presbyterian/Shadyside Hospitals The clinical laboratory I directed at UPMC performed a variety of screening and confirmatory drug of abuse testing.

3. This opinion is not made on behalf of or otherwise endorsed by the University of Iowa or UIHC and its affiliated hospitals and clinics.

4. I received my B.A with honors in East Asian Languages and Civilizations from the College of the University of Chicago in 1993. During college I also completed the coursework necessary for applying to medical school. During my first year of medical school, I

made the decision to train to become a physician-scientist and during my second year of medical school secured a competitive National Research Service Award grant from the National Institute of Mental Health (part of the National Institutes for Health or NIH) for combined MD and PhD training. After completing two years of medical school, I did doctoral training in Neurobiology (a graduate program within the Department of Pharmacology and Physiology), where I investigated the mechanism by which general anesthetics and related compounds affect the brain and spinal cord. I completed the PhD training in 3 years (degree awarded 1999) and, following that, returned to finish my last two years of medical school. In 2001, I received my MD with a Senior Scientific Award for excellence in research by an MD/PhD student

From 2001 to 2004, I was a resident in clinical pathology (laboratory medicine) at the University of Chicago Hospitals. I pursued clinical pathology to focus on toxicology and clinical chemistry, areas of pathology involved in analysis of drugs and drug metabolites that require a broad and detailed knowledge of pharmacology and chemistry. From 2003 to 2005 (overlapping one year with my clinical pathology residency), I was in a fellowship in Clinical Pharmacology and Pharmacogenomics at the University of Chicago.

5. I am board-certified in clinical pathology (laboratory medicine) and was elected fellow of the College of American Pathologists. I am a member of the American Association of Clinical Chemistry, Academy of Clinical Laboratory Physicians and Scientists, and the American Society for Clinical Pathology. I have received a number of awards including the Lemuel J. Bowie Young Investigator Award (American Association of Clinical Chemistry), Young Investigator Award (Division of Toxicology and Therapeutic Drug Monitoring, American Association of Clinical Chemistry), Significant Achievement in the Creation and Delivery of Clinical Services Award (University of Iowa Hospitals and Clinics, Department of Pathology),

Paul E. Strandjord Young Investigator Award (Academy of Clinical Laboratory Physicians and Scientists), and Robert E. Priest Fellowship Award (University of Chicago). I serve on the Executive Committee for the Academy of Clinical Laboratory Physicians and Scientists.

6. I have served as a peer reviewer for pharmacology-related articles in a number of biomedical journals including *Analytica Chimica Acta*, *Analytical and Bioanalytical Chemistry*, *Current Drug Metabolism*, *Expert Opinion on Drug Metabolism and Toxicology*, *LabMedicine*, and *Toxicology Letters*.

7. I have published 61 primary research and 9 review articles in peer-reviewed biomedical journals as well as ten book chapters, including 9 articles and 3 book chapters that primarily focused on toxicology, drug of abuse testing, and/or therapeutic drug monitoring.

8. As part of my teaching activities at the University of Iowa and UIHC, I do lectures and other educational activities related to drug of abuse testing to medical students, medical residents and fellows, attending physicians, nurses, social workers, and pharmacists. As medical director of the Clinical Chemistry Laboratory at UIHC, I have been consulted by healthcare workers on questions related to drug of abuse testing, including testing in neonates (on urine or meconium) and women who are pregnant or who have recently delivered a baby or babies.

II. SUMMARY STATEMENT OF OPINIONS TO BE EXPRESSED

9. I understand that a complaint in this action is that Jameson Health System, Inc. and Lawrence County Children and Youth Services improperly acted upon the results of prenatal drug of abuse testing to remove a newborn from the care of the plaintiff.

10. The only positive result in the drug of abuse testing of both mother and infant was the detection of opiates (specifically morphine) in the urine of the mother during a prenatal drug test. This was done using a urine drug of abuse screening test that had a cutoff of 300 ng/mL for opiates. Confirmatory testing performed by a reference laboratory (Quest Diagnostics, Pittsburgh, PA) only demonstrated the presence of morphine but did not provide an exact concentration. The opiate confirmatory testing has a lower limit of 100 ng/mL so the only conclusion that can be drawn from the confirmatory testing is that morphine was present at a concentration in urine of 100 ng/mL or greater.

Drug of abuse testing on meconium from the infant of the plaintiff was entirely negative for the presence of five main classes of drugs (amphetamines, marijuana, cocaine, opiates, and PCP). Meconium (first stool passed by the infant) accumulates drugs and their associated metabolites from drug use by a mother during pregnancy. The meconium testing on the plaintiff's infant was performed by reference laboratory (Quest Diagnostics, Chantilly, VA) and can detect the following opiates: morphine, codeine, hydrocodone, hydromorphone, and oxycodone. The absence of any drugs (including opiates) detected by analysis of the meconium of the infant argues against drug abuse by the mother during pregnancy.

11. The medical records indicate that the mother reported that she ingested a linguini salad that contained a seasoning (Salad Supreme®) that contains poppy seeds. As discussed below, ingestion of foods containing poppy seeds is well established in medical and scientific literature extending back 25 years to be a recognized cause of opiates-positive urine drug of abuse screens, especially using a 300 ng/mL cutoff for opiates. However, there is no documentation from the records of either Jameson Health System, Inc. and Lawrence County Children and Youth Services of any consideration that the presence of morphine in the mother

could be due to a dietary reason and not to drug abuse. Based on the lack of any documentation of suspicions of drug abuse by the mother, it appears the presence of morphine in the urine, a laboratory finding that could be due to multiple legitimate reasons including dietary consumption of foods containing poppy seeds, was the sole finding used to justify removing the infant from the custody of the plaintiff.

12. The detection of morphine in the urine of the mother is entirely consistent with the consumption of food containing poppy seeds by the mother. Multiple published scientific studies have established this, with publications on this phenonomenon dating back to the late 1980s.

III. SCIENTIFIC BACKGROUND

13. Drug of abuse testing (including in pregnant women) often uses urine as the specimen. Urine accumulates most of the commonly abused classes of drugs such as amphetamines, benzodiazepines, cocaine, opiates, phencyclidine ("PCP") and cannabinoids (e.g., marijuana). Laboratory testing may detect the parent drug (i.e., the original drug ingested or otherwise administered) or drug breakdown products that are known as metabolites.

14. Drug of abuse testing of newborn infants (neonates) may include analysis of urine but also may include analysis of meconium, which is the first stools (feces) passed by the newborn. Meconium is a complex material that accumulates over the last 4-5 months of pregnancy. Drugs or drug metabolites found in meconium can thus potentially reflect drugs used by the mother during the last 4-5 months of pregnancy. Opiates are one of the classes of drugs that may be detected in meconium

15. Opiates are a class of drugs that are found in the opium poppy plant. Poppy seeds contain a number of opiates including morphine and codeine. Morphine is usually the major alkaloid compound found in opium poppy. Morphine, codeine, and a variety of synthetic opiates (e.g., hydrocodone, hydromorphone, oxycodone) are widely used for medical purposes in the United States. Morphine, codeine, hydrocodone, hydromorphone, and oxycodone are all scheduled drugs regulated by the Controlled Substances Act. Typically, these opiates require prescription by physician or other licensed healthcare provider; however, codeine can be sold legally over-the-counter in some states without a prescription.

16. *Drug of abuse screening tests* generally use techniques such as immunoassays to look for the presence of classes of drugs such as opiates. Screening tests have the ability to detect multiple drugs and their metabolites within a class. Consequently, a screening test for opiates may be positive in a person who has morphine in their urine but could also be positive in another person who has a different opiate such as hydrocodone in their urine. Drug of abuse screening tests can have false positives, meaning a positive result caused by something other than the class of drugs being screened for. Screening tests have defined cutoff concentrations for drugs which define whether the results are negative or presumptive positive. A common cutoff for opiates screening tests used in the medical setting is 300 ng/mL for morphine.

17. In some medical settings, positive drug of abuse screening tests are followed by *confirmatory drug of abuse testing*. These generally use methods such as gas chromatography/mass spectrometry or liquid chromatography/tandem mass spectrometry that can definitively identify drugs or drugs metabolites. For example, while a drug of abuse screening test may be able to show only that opiates are likely present in a urine sample, a

confirmatory test can specifically identify morphine and further measure how much morphine is present.

18. Morphine is a drug found in the opium poppy plant. Morphine is a common prescription medication in the United States and used extensively within hospitals and also for outpatient treatment (e.g., therapy of chronic pain). Morphine is also a metabolite of some other drugs, most notably codeine, which is also a very common medication. Codeine is used for treatment of pain, as a cough suppressant, and occasionally for the treatment of diarrhea.

19. The ability of foods containing poppy seeds to cause positive opiate drug of abuse screening tests, particularly using a cutoff concentration for morphine of 300 ng/mL, has been known since at least the 1980s. Multiple published studies have looked at people who have consumed various foods containing poppy seeds (e.g., bakery goods such as bagels or muffins, or foods using poppy seed paste or seasonings) and examined their urine for presence of morphine, codeine, and sometimes other opiates. At least eleven studies published in the timeframe from 1987 to 2009 have shown that morphine concentrations in urine can exceed 300 ng/mL following consumption of foods containing poppy seeds (References A-K). In some cases, morphine concentrations in excess of 2,000 ng/mL have been described following ingestion of foods containing poppy seeds. Consequently, consumption of food products containing poppy seeds is well-known to be a potential cause of positive opiates drug of abuse screens.

IV. REFERENCES

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(B) Hayes LW, Krasselt WG, Mueggler PA. Concentrations of morphine and codeine in serum and urine after ingestion of poppy seeds. Clinical Chemistry 33: 806-808, 1987.

(C) Jankovičová K, Ulbrich P, Fuknová M. Effect of poppy seed consummation on the positive results of opiates screening in biological samples. Legal Medicine 11: S416-S418, 2009.

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(E) Meadway C, George S, Braithwaite R. Opiate concentrations following the ingestion of poppy seed products – evidence for the 'poppy seed defence'. Forensic Science International 96: 29-38, 1998.

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(H) Struempler RE. Excretion of codeine and morphine following ingestion of poppy seeds. Journal of Analytical Toxicology 11: 97-99, 1987.

(I) Thevis M, Opfermann G, Schänzer W. Urinary concentrations of morphine and codeine after consumption of poppy seeds. Journal of Analytical Toxicology 27: 53-56, 2003.

(J) Trafkowski J, Madea B, Musshoff F. The significance of putative urinary markers of illicity heroin use after consumption of poppy seed products. Therapeutic Drug Monitoring 28: 552-558, 2006.

(K) Zebelman AM, Troyer BL, Randall GL, Batjer JD. Detection of morphine and codeine following consumption of poppy seeds. Journal of Analytical Toxicology 11: 131-132, 1987.

V. COMPENSATION

I am being compensated for my work in this case at a rate of $100/hour/

VI. PREVIOUS TESTIMONY IN LAST 4 YEARS

1. **Pfizer Inc., Pharmacia & Upjohn Company, and Pfizer Health AB (plaintiffs) v. Teva Pharmaceuticals USA, Inc., United States District Court for the District of New Jersey, Civil Action No. 04-1418**

   Expert witness for plaintiffs

   Deposition November 2006

   Testified at trial September 2009

2. **K-Dur Antitrust Litigation, United States District Court for the District of New Jersey, Case No. 01-CV-1652-JAG**

   Expert witness for defendent Upsher-Smith Laboratories

   Deposition March 2008

3. **State of Iowa v. Lynne and Roger Holdeman, Polk Country, Iowa, insurance fraud**

   Expert witness for co-defendant Roger Holdeman

   Deposition March 2009

   Testified at trial April 2009